REMARKS

Claims 1-20 stand rejected in the subject application. Claims 1 and 9-10 have been amended to delete "chamber" and replace it with "container." Support for the amendment is found throughout the specification, such at least at page 4, lines 24-33. Claims 11-12, and 19 have been amended to delete "chamber" and replace it with "enclosure." Support for the amendment is found throughout the specification, such at least at page 4, lines 24-33. Claims 2-10 have also been amended to correct matters of form. Applicants submit that no new matter has been introduced.

A. Rejection of Claims 1-7 and 9-20 under 35 U.S.C. § 102(b)

Claims 1-7 and 9-20 stand rejected under 35 U.S.C. §102(b) as assertedly being anticipated by EP 0373201 to Cummings (hereinafter "Cummings"). Applicants traverse this rejection for the reasons set forth herein.

Independent claim 1 and the claims that depend therefrom, recite a method of disinfecting or sterilizing an article. The method comprises: placing the article into a container; reducing pressure in the container to a first pressure; introducing a mist comprising a sterilant into the container; and diffusing the mist through the container into contact with the article. Claim 1 further recites that the first pressure is below atmospheric pressure and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the container. Independent claim 11 and the claims that depend therefrom, recite a method of disinfecting or sterilizing an article. The method comprises: placing the article into an enclosure; and reducing pressure in the enclosure to a first

pressure to disperse a mist comprising a sterilant throughout the enclosure and into contact with the article. The enclosure can be any enclosed area that can withstand a reduction of pressure to disperse a mist.

The Examiner asserts that Cummings teaches each and every element recited in claim 1 of the subject application. In particular, the Examiner asserts that Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items comprising: placing articles into the chamber, reducing pressure in the chamber to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure, introducing a sterilant as a mist into the chamber and diffusing the mist through the chamber into contact with the articles (Office Action, page 2, paragraph 3). In addition, the Examiner asserts that Cummings teaches each and every element recited in claim 11 of the subject application. In particular, the Examiner asserts that Cummings discloses a method of sterilizing an article comprising: placing the article into a chamber; and reducing pressure in the chamber to a first pressure then introducing hydrogen peroxide vapor into the sterilization chamber (Office Action, page 3, paragraph 2).

For the rejection of claims 1 and 11, the Examiner asserts that the vapor disclosed in Cummings and mist in the subject application are equivalent because vapor and mist are synonyms (Office Action, page 2, paragraph 3 and page 3, paragraph 2). Applicants respectfully disagree that vapor and mist are synonyms; at least for this reason, Applicants respectfully disagree that Cummings teaches each and every element of claims 1 and 11.

In this regard, Applicants submit herewith the Declaration of Dr. Szu-Min Lin under 37 C.F.R. § 1.132 that explains several critical physical and chemical distinctions between

mist and vapor. First, Dr. Lin states that a mist is made up of small droplets of liquid, whereas vapor is gas made up of free molecules. Dr. Lin further states that although a mist may vaporize ultimately into a vapor, mist is not the same as vapor just as water in liquid phase may vaporize into vapor. Second, Dr. Lin states that vapor may condense, whereas mist does not condense. Third, Dr. Lin states mist and vapor differ according to their physical size and weight. For example, mist may be generated with the use of an ultrasound humidifier. The size of water droplets of a mist generated with ultrasound is typically around 2-10 microns (2-10 $x10^{-6}$ meter), which is visible and significantly larger than water vapor. In contrast, Dr. Lin further states that the water vapor that vaporizes from liquid water is invisible and can diffuse freely in the air. Furthermore, as noted in the Declaration, the bond length between oxygen and hydrogen in a water molecule is only about $1x10^{-10}$ meter. Dr. Lin further states that one 5-micron droplet of water mist weighs about $6.5x10^{-11}$ g and can actually produce more than one trillion free molecules. In contrast, each water vapor molecule weighs about $3x10^{-23}$ g. As declared by Dr. Lin, the difference in physical size between mist and vapor is extremely critical for sterilization purposes. Due to the difference in physical size, sterile packaging materials are only porous enough to allow the penetration of vapor, but not mist.

In addition, Dr. Lin states that mist and vapor compositions of hydrogen peroxide are derived from an aqueous composition of hydrogen peroxide. As indicated in Table 18 of W.C. Schumb, *et al.* "Hydrogen Peroxide," pages 221-227 (Reinhold pub. 1955) (hereinafter, "Schumb"), attached hereto as Exhibit A, Dr. Lin states that mist and vapor compositions differ based on the concentration of hydrogen peroxide in each. For

example, 50% liquid composition of hydrogen peroxide can only produce about 7% vapor peroxide at 10°C and 12% at 70°C, whereas 50% liquid composition can produce 50% mist composition regardless of the temperature. Dr. Lin states that the concentration of the mist composition of hydrogen peroxide is always the same as the concentration of liquid composition from which it is derived. However, based on Dr. Lin's vast experience and supported by the teachings of Schumb, this is not true for vapor compositions. Instead, in an enclosed system, the vapor composition of hydrogen peroxide is always less than the concentration of liquid composition from which it is derived until the liquid is completely vaporized.

Therefore, Dr. Lin states that peroxide mist is different from peroxide vapor based on phase (liquid vs. gas), physical size, physical weight, ability to penetrate sterile packaging material, and composition. Hence, Dr. Lin states that the Examiner is factually incorrect with his assessment that the mist disclosed in the above referenced subject application and the vapor of Cummings are synonymous.

For a reference to be anticipatory under 35 U.S.C. § 102, it is axiomatic that the reference or combination of references teach, either explicitly or inherently, each and every element of the invention as set forth by the claims. Cummings does not teach a method of disinfecting or sterilizing an article comprising the use of a mist, as recited in the present claims 1-20. For at least this reason, Cummings does not anticipate independent claims 1 and 11 or any of the claims dependent therefrom.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-20 under U.S.C. § 102(b) over Cummings.

B. Rejection of Claim 8 under 35 U.S.C. § 103(a)

Claim 8 stands rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Cummings further in view of U.S. Patent No. 5,785,934 to Jacobs *et al.* (hereinafter "Jacobs"). Applicants respectfully traverse the rejection for at least the reasons as set forth herein.

Cummings is clearly distinct from claim 8, which depends from claim 1, for at least the reasons set forth in *Section A*, above. Furthermore, Jacobs provides no teaching that, when combined with Cummings, would lead one of ordinary skill in the art to Applicants' claimed method of disinfecting or sterilizing an article comprising, in part, reducing pressure in the container to enhance diffusion of the mist throughout the container. Indeed, the Examiner only cites Jacobs for the teaching of inoculating stainless steel blades with *Bacillus stearothermophilus* (Office Action, pages 5-6).

Thus, a *prima facie* case of obviousness for claim 8 in view of the combination of teachings of Cummings and Jacobs has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 8 under 35 U.S.C. §103(a) in view of Cummings and Jacobs.

CONCLUSION

For at least the reasons discussed above, Applicants respectfully request reconsideration of the rejections and allowance of claims 1-20. Applicants respectfully submit that the present claims are clearly distinguished over the prior art of record and are

in proper form for allowance.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below. Applicants submit that if any additional fee is necessary for consideration of this Response, the Commissioner is hereby authorized to charge the additional required fees to Account No. 11-1110.

Respectfully submitted,

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Date

Sean M. Conrad
Sean M. Conrad
Patent Agent
Registration No. 61,532

K&L GATES LLP
Henry W Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222-2312
Phone: 412.355.6218
Fax: 412.355.6501

Customer No.: 26,285